



American Society for Quality (www.asq.org) – Washington DC and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group (SIG) Meeting

“Big Ears vs Large Antennae – When USA and Japan Work Together”

To be presented by

Fortunato Fred Senatore, MD, PhD, FACC

Medical Officer (fortunato.senatore@fda.hhs.gov)

Office of New Drugs, Division of Cardiovascular and Renal Products

Center for Drug Evaluation and Research (CDER), US FDA

Thursday, January 24, 2013

6:00 – 6:20 PM – Networking; Pizza/drink

6:20 – 8:30 PM – Program (intermission at 7:40 pm)

8:30 – 8:45 PM – Door-prizes drawing; Networking

Online Registration site: <http://www.asq509.org/ht/d/DoSurvey/i/35817>

Open to Public –

\$5: non-ASQ members to cover pizza/drink cost;

Free: ASQ Members, MJ-DC Members, veterans, senior citizens, students, interns, residents, postdocs, FDA Commissioner’s Fellows, and current job-seekers

Location: Kelly’s Deli Conference Center, 7519 Standish Place, Rockville (Derwood, for GPS user), MD 20855

Registration Deadline: Please register by **Thursday noon, January 24, 2013.**

Question: Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; gchang2008@yahoo.com or 240-793-8425 (cell).

Driving directions: By Car: From I-270 (N or S bound): Take Exit 9A and exit from the FIRST right exit; turn left (east) onto Shady Grove Dr.; turn right (south) onto Rockville Pike (**Route 355**); turn left (east) onto East Gude Dr.; turn left (north) immediately onto Crabb’s Branch Dr.; turn left (west) immediately onto Standish Place. The first building on your right side is 7519 Standish Place; open parking). **The venue is on the first floor with its entrance opposite to the left side of building main entrance.** **By Metro train:** Off from Red Line **Shady Grove Station**, and take RideOn **Route 59 TOWARD ROCKVILLE** and get off from “**Calhoun Place**” stop. Standish Place is next to the Bus stop. Our venue is within 2 min of walking distance from the stop.

Summary:

This presentation examines Asian and Western **cultural attributes** and how such attributes impact **working relationships** in a global corporate environment. Although focused on Japanese-American relations, the issues discussed have general applicability to Asian-Western (i.e. American and European) relations.

The presentation covers philosophical approaches to “self and ideas” (i.e. the Confucius versus Socratic principles), communication techniques, listening strategies, and uncovering the message behind the communication style, the concept of “big ears versus large antennae”, consensus strategies, how to disagree politely and how to “save face” when a society with a penchant for bluntness meets a society whose communication paradigm is blunt averse. The presentation ends with a mock global meeting which illustrates **pitfalls** and recommends **remediation strategies** for optimizing cross-cultural sensitivity.

Presenter's Bio:

Dr. Fortunato Fred Senatore was born in Brooklyn NY to immigrant parents and grew up in Brooklyn. Following high school graduation as valedictorian and years of study at the *Brooklyn Academy of Music*, he attended *Columbia University* and received a BA in Biochemistry and two years later, a MS in Bio-engineering. He received his PhD from *Rutgers University* in Chemical Engineering. He **taught** Chemical Engineering at *Texas Tech University* for 8 years and focused his **research** on artificial organ technology, biocompatibility with biological devices, fluid mechanics, hemodynamics, and modeling/simulation of biological processes. While a **Professor** of Chemical Engineering, he simultaneously attended Medical School at the Texas Tech University Health Sciences Center School of Medicine. Upon graduation, he matched at the *Mayo Clinic* for Internal Medicine Residency Training, and later at *Harvard* for Cardiology Fellowship at the *Massachusetts General Hospital* (MGH). While at MGH, he participated as **Investigator/sub-investigator** in cardiovascular clinical trials.

Dr. Senatore was recruited to *Merck* as **Associate Director** in the Cardio-Renal Division. He designed clinical trials and developed clinical strategies and plans for Aggrastat for ACS, Cozaar for hypertension and heart failure, Endothelin-Receptor Antagonist for pulmonary hypertension, Fibroblast Growth Factor for peripheral vascular disease, and Thrombin-Inhibitor for stroke prevention in non—rheumatic atrial fibrillation, as well as DVT prophylaxis. He was ultimately promoted and served as **Head** of Thrombosis in Cardio-Renal at Merck. Fred moved to *Aventis* as **Senior Director** and **Global Team Leader** for Ramipril and Apidra. He “walked into” the HOPE trial for prevention of major adverse cardiac events for subjects with risk factors, which had already started during his assumption of leadership. He also developed the strategy and supervised the execution of the clinical plans for Apidra (rapid-acting insulin for T1 and T2 diabetes mellitus) which resulted in approval by the FDA. Fred moved to *Sankyo* as **Executive Director** and **head** of Sankyo’s cardio-renal-metabolic division, where he was responsible for ACAT-inhibition (Phase 3 program showed that ACAT-inhibition is actually harmful), ADP-Receptor Antagonism (i.e. Prasugrel trials with TIMI and Eli Lilly—JUMBO and TRITON), Protein-kinase-delta inhibitor for myocardial salvage in acute myocardial infarction, and Welchol for diabetes. He then was recruited to *Mitsubishi* where he served initially as **Executive Director** of Cardio-Renal-Metabolic Therapeutic Areas, and later as **Head** of Clinical Science. He worked closely with Mitsubishi Headquarters in Japan on the clinical development plans and execution of a variety of initiatives, none of which resulted in an NDA. Following multiple interactions with the FDA from the Sponsor side, he developed a strong respect for the intellectual caliber, insightfulness, and dedication to the public health exemplified by the FDA staff. He explored the possibility of employment with the FDA and was honored to have joined *FDA/CDER*/Office of New Drug/Division of Cardiovascular and Renal Products in September 2012 as a **Medical Officer**.

This event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington (www.MonteJadeDC.org).